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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,350	06/04/2001	Beverly S. Packard	300-903840US	3770

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 08/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/874,350

Applicant(s)

PACKARD ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 39-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/31/02; 3/17/03; 4/1/03; 6/26/03

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

Election/Restrictions

2. Applicant's election of Group I, claims 1-38 and the sequence of YVHDAPV (SEQ ID NO:210) in the reply filed on May 09 and June 20, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Since the sequence of YVHDAPV as the "P" domain is encompassed by the sequences in claims 4 and 24, and the sequence dYVHDAPV having a d-isomer of Y in YVHDAPV (claim 21), thus, the sequences in claims 4, 21 and 24 will be considered. Claims 39-61 and 8 (containing non-elected sequence) are non-elected invention and withdrawn from consideration. Therefore, claims 1-7 and 9-38, SEQ ID NO:210 and the sequences containing SEQ ID NO:210 are examined.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because it lists the priority documents PCT/US00/24882 and PCT/US98/03000 as foreign applications under 35 U. S. C. 119, these documents are not foreign applications and should be listed under 35 U. S. C 120.

Informalities

The disclosure is objected to because of the following informalities:

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4. The specification recites formula V at page 25, which uses subscripts in F_1 and F_2 , while the definition for the formula uses superscripts in F^1 and F^2 . Appropriate clarification is required.

5. Table 4 recites substrate sequences such as SEQ ID NO:170, 171 and 172 for caspase-1 (at page 30); and it appears the amino acid sequences of SEQ ID NO:170 and 171 are the same, and the sequence of SEQ ID NO:172 at page 30 is not consistent with the sequence in the Sequence Listing. Furthermore, two sequences (KDPJGYVHDAPVPGKY, and KDPYVHDAPVGJPKGY) in claim 4 are not listed in the Sequence Listing; and two sequences KDBJGWHADAPVGJPKGY (which is not SEQ ID NO: 217, but is similar to SEQ ID NO:220 except at position 3), and KDBJGdYVHDAPVGJPKGY (which is not SEQ ID NO: 218, but is similar to SEQ ID NO:221 except at position 3) in claim 24 are also not in the Sequence Listing. Applicants must comply with the requirements of the sequence rules (37 CFR 1.821-1.825) and provide a copy of sequence listing and CRF containing all the sequences.

Claim Objections

6. Claim 1 is objected to because the claim contains non-elected sequences.

7. Claim 4 recites amino acid sequences without providing "SEQ ID NO:". Appropriate correction is required.

8. Claims 13 and 32 are objected to because the claim recites 9-(2,5 (or 2,6)-dicarboxyphenyl)-3,6-bis(dimethylamino)xanthyliumhalide and 9-(2,5 (or 2,6)-dicarboxyphenyl)-3,6-bisamino-xanthylium halide, which contain either 2,5-dicarboxyphenyl isomer or 2,6-dicarboxyphenyl isomer and should be cited separately since they are two different groups.

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9. Claims 17 and 35 are objected to because of misspelling or incorrect formula of "4,4=-dimethoxy", "4,4-dimentyl" or "2,6-diaxocyclohexylidene" in the term "4,4=-dimethoxybenzhydryl (Mbh)" or "1-(4,4-dimentyl-2,6-diaxocyclohexylidene)ethyl (Dde)". The term Mbh or Dde reads as a group having a right chemical name. A fully spelled chemical name should be cited for Fmoc in the first occurrence (claim 7).

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-7 and 9-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 5-13 of U. S. Patent 6,037,137. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-7 and 9-38 in the instant application disclose a fluorogenic composition for the detection of the activity of a protease having the formula cited in claim 1, where P is a peptide having a sequence such as YVHDAPV, F¹ and F² are fluorophores, S¹ and S² are spacers, aa¹, aa¹⁰, aa², aa³, aa⁸, aa⁹, aa⁵, aa⁴, aa⁶, aa⁷, X and Y are defined in the claim. This is obvious in view of claims 1 and 5-13 in the patent which disclose a fluorogenic composition for the detection of the activity of a protease having the formula cited in claim 1, where P is a peptide comprising a

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protease binding site for the protease, F^1 and F^2 are fluorophores, S^1 and S^2 are spacers, aa^1 , aa^{10} , aa^2 , aa^3 , aa^8 , aa^9 , aa^5 , aa^4 , aa^6 , aa^7 , X and Y are defined in the claim. Both sets of claims cite a fluorogenic composition for the detection of the activity of a protease having the formula, wherein P is a peptide comprising a protease binding site for the protease, e.g., YVHDAPV. Thus, claims 1-7 and 9-38 in present application and claims 1 and 5-13 in the patent are obvious variations of a fluorogenic composition for the detection of the activity of a protease, which contains a peptide having a protease binding site such as YVHDAPV.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-7 and 9-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
12. Claims 1-7 and 9-38 are indefinite because claims 1 and 21 recite " aa^2 , aa^3 , aa^8 and aa^9 are independently selected from the group consisting of an amino acid or a dipeptide", however, there are no dipeptides *per se* cited in the Markush group "selected from the group consisting of Asp, Glu,... Thr, and Tyr.". In claims 1 and 21, the formula uses subscripts in F_1 and F_2 , while the definition in the claim uses superscripts in F^1 and F^2 , since they are not the same, it is unclear which is the correct one? Claims 2-7, 9-20 and 22-38 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

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13. Claims 4-7 and 24-27 are indefinite as to the cited sequences do not conform the formula of claim 1 or 21. Claims 1 and 21 indicate aa^2 , aa^3 , aa^8 or aa^9 can be an amino acid, according to the formula, $(aa^2-aa^3)_k$ will be either a dipeptide or no amino acid residue since k is 0 or 1, however, the sequences (KDPJGYVHDAPVGJPKGY, KDPJGYVHDAPVPPKGY, and KDPYVHDAPVGJPKGY) in claim 4 and the sequences (KDBYVHDAPVPPKGY, KDBGYVHDAPVGPKGY, KDBJGWHHDAPVGJPKGY and KDBJGdYVHDAPVGJPKGY) in claim 24 would have D as (aa^2-aa^3) , thus, it appears these sequences do not conform the formula of claim 1 or 21. Claims 5-7 and 25-27 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

14. Claim 24-27 are indefinite as to the cited sequences (SEQ ID NOs:215, 216, 217 and 218) do not have the same amino acid sequence as the sequences with the same "SEQ ID NO:" in the Sequence Listing. Claims 25-27 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

15. Claims 6 and 27 are indefinite as to "Fa", it is not clear what "Fa" represents. A fully spelled chemical name should be indicated in the first occurrence.

16. Claim 19 recites the limitation "Fa" in line 1. There is insufficient antecedent basis for this limitation in the claim. See also claim 37.

Conclusion

17. No claims are allowed.

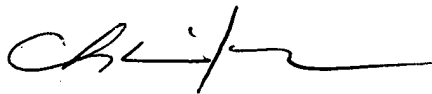
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner



**CHIH-MIN KAM
PATENT EXAMINER**

CMK

August 1, 2005